

Attorney Docket No.: 5784.210-US
USSN: 09/671,461
Filed: 09/27/2000
Inventor: Arne Staby

Amendments to the Claims:

The listing of claims will replace all prior versions, and listings, of the claims in the application:

Listing of Claims

Claim 1 (Cancelled)

Claim 2 (Amended) A method for purifying a peptide from a mixture comprising said peptide and related impurities, said method comprising:

- a) eluting said related impurities of said mixture from an anion exchange chromatography matrix using a solution comprising an organic modifier, water, optionally a salt component and optionally a buffer, at a linear or step gradient or isocratically in salt component, and at pH-values optionally maintained with a buffer so that said peptide has a negative local or overall net charge and said related impurities have a local or overall negative net charge which is lower than the negative net charge of said peptide so as to remove said related impurities; and
- b) subsequently, eluting said peptide in the absence of an organic modifier, by a step or linear change to an aqueous solvent optionally with a salt component, at the same or lower pH-values optionally maintained with a buffer.

Claim 3 (Cancelled)

Claim 4 (Amended) An industrial method for producing a pure peptide from a mixture comprising said peptide and related impurities, said method comprising:

- a) eluting said related impurities of said mixture from an anion exchange chromatography matrix using a solution consisting essentially of an organic modifier, water, optionally a salt component and optionally a buffer, at a linear or step gradient or isocratically in salt component, and at pH-values optionally maintained with a buffer so that said peptide has a negative local or overall net charge and said related impurities have a local or overall negative

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net charge which is lower than the negative net charge of said peptide so as to remove said related impurities; and

b) subsequently, eluting said peptide in the absence of an organic modifier, by a step or linear change to an aqueous solvent optionally with a salt component, at the same or lower pH-values optionally maintained with a buffer.

Claim 5 (Cancelled)

Claim 6 (Currently Amended) The method according to claim 1 further comprising subjecting the peptide eluted in step (b) to analytical tests or further purification.

Claims 7-10 (Cancelled)

Claim 11 (Currently Amended) The method of claim 2, wherein said peptide to be purified is selected from polypeptides, oligopeptides, proteins, and receptors, ~~as well as homologs, analogs and derivatives thereof.~~

Claim 12 (Currently Amended) The method of claim 2, wherein said peptide to be purified is selected from glucagon, hGH, insulin, FactorVII, FactorVIIa, FactorVIIa1, FFR-FactorVIIa, glucagon-like peptide-1, and glucagon-like peptide-2 ~~and analogs, as well as derivatives thereof.~~

Claim 13 (Previously Presented) The method of claim 2, wherein the ratio of organic modifier to water on a weight percent basis is from 1:99 to 99:1.

Claim 14 (Previously Presented) The method of claim 2, wherein the organic modifier is selected from C₁₋₆-alkanol, C₁₋₆-alkenol, C₁₋₆-alkynol, urea, guanidine, C₁₋₆-alkanoic acid, C₂₋₆-glycol, or C₃₋₇-polyalcohol.

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Claim 15 (Currently Amended) The method according to claim 1-2, wherein the peptide is selected from the group consisting of Val⁸GLP-1(7-37), Thr⁸GLP-1(7-37), Met⁸GLP-1(7-37), Gly⁸GLP-1(7-37), Val⁸GLP-1(7-36) amide, Thr⁸GLP-1(7-36) amide, Met⁸GLP-1(7-36) amide, Gly⁸GLP-1(7-36) amide, Arg³⁴GLP-1(7-37), and B28IsoAsp insulin.

Claim 16 (New) The method according to claim 4 further comprising subjecting the peptide eluted in step (b) to analytical tests or further purification.

Claim 17 (New) The method of claim 4, wherein said peptide to be purified is selected from polypeptides, oligopeptides, proteins, and receptors.

Claim 18 (New) The method of claim 4, wherein said peptide to be purified is selected from glucagon, hGH, insulin, FactorVII, FactorVIIa, FactorVIIai, FFR-FactorVIIa, glucagon-like peptide-1, and glucagon-like peptide-2.

Claim 19 (New) The method of claim 4, wherein the ratio of organic modifier to water on a weight percent basis is from 1:99 to 99:1.

Claim 20 (New) The method of claim 4, wherein the organic modifier is selected from C₁₋₆-alkanol, C₁₋₆-alkenol, C₁₋₆-alkynol, urea, guanidine, C₁₋₆-alkanoic acid, C₂₋₆-glycol, or C₃₋₇-polyalcohol.

Claim 21 (New) The method according to claim 4, wherein the peptide is selected from the group consisting of Val⁸GLP-1(7-37), Thr⁸GLP-1(7-37), Met⁸GLP-1(7-37), Gly⁸GLP-1(7-37), Val⁸GLP-1(7-36) amide, Thr⁸GLP-1(7-36) amide, Met⁸GLP-1(7-36) amide, Gly⁸GLP-1(7-36) amide, Arg³⁴GLP-1(7-37), and B28IsoAsp insulin.